

W=100 mm

Vildapin™

Tablet

Vildagliptin

Description

Vildagliptin is a potent and selective dipeptidyl peptidase-4 (DPP-4) inhibitor. It rapidly and completely inhibits DPP-4 activity and thus increases the levels of two incretin hormones GLP-1 (Glucagon-like peptide-1) and GIP (Glucose dependent insulinotropic polypeptide). Thus it enhances the sensitivity of beta cells to glucose, resulting in improved glucose-dependent insulin secretion. It also enhances the sensitivity of alpha cells to glucose by increasing endogenous GLP-1 levels, resulting in reduced glucagon secretion. The increase in the insulin/glucagon ratio during hyperglycemia due to increased incretin hormone levels results in a decrease in fasting and postprandial hepatic glucose production leading to reduced glycemia.

Composition

Each film-coated tablet contains Vildagliptin INN 50 mg.

Indications

Vildapin™ is indicated for the treatment of type – 2 Diabetes mellitus.

- As monotherapy
- In dual combination with Metformin, a sulfonylurea, a Thiazolidinedione or insulin when diet, exercise and a single anti-diabetic agent do not result in adequate glycemic control.

Dosage and Administration

Vildapin™ can be administered with or without food.

As monotherapy and in dual combination with Metformin, a Thiazolidinedione or insulin : 50 mg or 100 mg daily. The 50 mg dose should be administered once daily in the morning and the 100 mg dose should be administered as two divided doses of 50 mg in the morning and evening.

In combination with a sulfonylurea : 50 mg once daily administered in the morning.

Dosage in renal impairment :

For mild renal impairment (Creatinine clearance ≥ 50 ml/min) : No dose adjustment is required.

For moderate to severe renal impairment : 50 mg once daily. For hemodialysis patients with end-stage liver disease should be used with caution.

Dosage in hepatic impairment : Should not be used in patients with hepatic impairment.

Or as directed by the physician.

Contraindication

Contraindicated in patients with known hypersensitivity to vildagliptin or any of the excipients.

Side effects

The most common side effects are nausea, peripheral edema, headache, tremor, asthenia and dizziness.

Precautions

- Vildagliptin is not a substitute for insulin in insulin requiring patients
- Should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
- Liver function should be monitored before treatment and every 3 months for first year and periodically thereafter.
- Should be used with caution in patients with heart failure.

Use in Pregnancy and Lactation

Pregnancy : Pregnancy Category B. There are no adequate and well- controlled studies in pregnant women. Vildagliptin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation : It is not known whether Vildagliptin is excreted in human milk. It should not be exercised administered to a nursing mother.

Pediatric Use

Safety and effectiveness in children have not been established.

Drug interaction

Vildagliptin has a low potential for drug interactions. Vildagliptin is not a cytochrome P450 enzyme substrate and it does not inhibit or induce cytochrome P450 enzymes. So it is not likely to interact with co-medications that are substrates, inhibitors or inducers of these enzymes. No clinically relevant interactions with other oral anti diabetics (Glibenclamide, Pioglitazone, Metformin), Amlodipin, Digoxin, Ramipril, Simvastatin, Valsartan or warfarin were observed after co-administration with vildagliptin.

Supply

Each box contains 2x10 tablets in alu-alu blister pack.

Keep all medicines out of reach of the children.
Store in a cool and dry place, protected from light.

*Further information is available on request

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Manufactured by:
The ACME Laboratories Ltd.
Dhamrai, Dhaka, Bangladesh

For Health, Vigour and Happiness